REMARKS

Status of the Claims

Claims 76-92, 94-104, and 106-109 are pending in the application. Claims 76-91 and 98-104 are currently withdrawn from consideration. Claims 92, 94-97, and 106-109 stand ready for further action on the merits. In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Drawings

Since no objection has been received, Applicants assume that the drawings are acceptable and that no further action is necessary. Confirmation thereof in the next Office Action is respectfully requested.

Issues under 35 U.S.C. § 102(b)

Claims 92, 97, and 106 are rejected under 35 U.S.C. § 102(b) as being anticipated by Finke '090 (CA 2394090). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Distinctions over the Cited Reference

The Examiner asserts that 2,3'-sialyl lactose of Example 4 and lacto-N-neo-tetraose of Example 5 of Finke '090 disclose the two species elected in the present invention. However, these two oligosaccharide fractions come from two separate examples in Finke '090. As such, Finke '090 fail to disclose that the oligosaccharide fractions of Examples 4 and 5 are combined. In other words, Finke '090 does not anticipate the oligosaccharide composition defined in the present invention and the claimed method of treatment of gastrointestinal infection wherein said oligosaccharide composition is administered.

Furthermore, Applicants respectfully assert that Finke '090 merely recites, on very general terms, the known general bioactivities associated with human milk oligosaccharides and known facts about the presence of the same oligosaccharides in animal milks. Finke '090 fails to disclose any effect with respect to any pathogen or disease. Moreover, the disclosure of Finke '090 of oligosaccharide compositions based on mixing fractions from animal milks is so broad that one of ordinary skill in the art would not arrive at the present invention based on Finke '090. In contrast, the present specification and the claims recite particular oligosaccharide sequences that have activity against specific gastrointestinal pathogens and disclose oligosaccharide combinations of these.

On the other hand, Finke '090 disclose mixing at least two oligosaccharide fractions comprising at least two different oligosaccharides including neutral and/or acidic oligosaccharides to obtain a mixture comprising acidic and neutral saccharides in certain ratio. Finke '090 is unclear as to which fractions are neutral or acidic or both and provides no disclosure as to what would be the exact components of the mixed saccharide combinations. Since the terms "neutral" and "acidic" are chemically very broad terms including very heterogeneous groups of glycans with a number of activities, Finke '090 does not disclose any exact oligosaccharide composition. In fact, Finke '090 only lists a few rather vague examples. Therefore, Finke '090 leads to an indefinite number of saccharide combinations, most of which are likely inactive with respect to the medical indications suggested since many oligosaccharides do not have a medical effect as shown by the present invention. Consequently, those combinations of Finke '090 which would be effective towards some specific pathogen would have such an effect only by chance.

One of ordinary skill in the art would know that natural human milk contains a great number of oligosaccharide species and that human milk has a positive effect to gastrointestinal health. Finke '090 discloses that this same effect may be achieved by mixing fractions of animal milks, which are known to contain oligosaccharides of human milk, but does not disclose any data about which oligosaccharide species are effective and which are not. Therefore, one of ordinary skill in the art would not arrive at the present invention based on the disclosure of Finke '090.

Human influenza virus hemagglutinin, which binds Neu5Acα6Lactose, can be used as an example. This saccharide, when in high concentration, is known to inhibit the Neu5Acα6-dependent sialic acid binding of hemagglutinin and consequently the binding of the virus to host tissue. However, administration of 4 or more oligosaccharides without the binding activity (other sialic acid linkages or neutral saccharides) would not be effective. In the case that the composition of Finke '090 would comprise Neu5Acα6Lact, restricting its amount only to a fraction of the composition (as acid glycans or a part thereof) would lead to reduction of the amount of active compound and thus to weak or no activity.

Therefore, Finke '090 does not disclose the selection or any specific example of the structurally defined oligosaccharide combinations of the present invention. Accordingly, the present invention is not anticipated by Finke '090 since the reference does not teach or provide for each of the limitations recited in the pending claims.

Issues under 35 U.S.C. § 103(a)

Claims 94-96 and 107-109 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Finke '090 in view of Zopf or Pickering et al. (Infection 21 (1993) No. 6, pages 355-357). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

(a) determining the scope and content of the prior art;

(b) ascertaining the differences between the prior art and the claims in issue;

(c) resolving the level of ordinary skill in the pertinent art; and

(d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

Distinctions over the Cited References

The Examiner alleges that Finke '090 would have disclosed the combination of oligosaccharides and that Zopf or Pickering et al. disclose the specific indications for these combinations. Applicants respectfully traverse this assertion. As discussed above, there is no active single substance called "oligosaccharides." Rather, oligosaccharides are a very large group of chemical compounds with different structures and different bioactivities.

Based on Finke '090, the oligosaccharide composition must be designed so that an increased effect is obtained (page 4, lines 8-10). The oligosaccharide composition of Finke '090 should not correspond to the original mixture present in an animal milk or present in several milks (page 4, lines 10-13). Therefore, Finke '090 discloses that an original oligosaccharide composition from an animal does not have "an increased biological effect." Thus, the composition of Finke '090 should be different from any native animal oligosaccharide mixture in milk.

On the other hand, animal milk oligosaccharides are very heterogeneous compositions varying between individual animals, and during lactation, there are numerous species of mammalian and marsupial animals producing milk, wherein its ingredients are species specific. To produce an active composition according to Finke '090, one of ordinary skill in the art should analyze all possible animal milks and not produce ones which could exist in any animal. Such composition is extremely unlikely and practically impossible to exist. In addition, the number of suggested oligosaccharide mixtures of Finke '090 is infinite, and the number of inactive compositions based on Finke '090 is endless and infinite. Therefore, one of ordinary skill in the art would not arrive at the present invention based on Finke '090 when combining fractions of Finke '090 or trying to combine Finke '090 with any other data.

Turning specifically to Finke '090 in view of Zopf, as discussed above, Finke '090 discloses only mixes of oligosaccharide fractions from animal milks without any data of the effects of certain oligosaccharide species with respect to any pathogen or disease. Zopf does not disclose that oligosaccharides in general would be active against H. pylori or E. coli. On page 1017 of Zopf, a table indicates that certain saccharides would be effective against H. pylori and E. coli.

With respect to H. pylori, the effective saccharide is defined on page 1019 as NE-080, which is a sialyl-lactose. However, the present invention is not directed to the human gastric pathogen H. pylori. Rather, the present invention is directed to diarrheagenic non-H. pylori Helicobacter species (i.e. *zHelicobacter*).

Regarding the E. coli species, the species includes the binding to Galα4Gal which would be effective against papG adhesin of uropathogenic E. coli, which causes urinary tract infections (distinct from the diarrheagenic species) (page 1018, first column, first paragraph). Zopf also discloses inhibitory activity of NeuGlycolyl-neuraminic (Neu5Gc) acid containing glycopeptides, which are effective against K99 E. coli, which is not a human pathogen but a pathogen for piglets, calves, and lambs (page 1018, first column, second paragraph). Also, Neu5Gc is a xenoantigen not naturally synthesized in humans, and the K99 pathogen is species specific. Thus, Zopf does not provide any relevant disclosure for human diarrheas. Moreover, Zopf shows that each pathogen has its own carbohydrate binding profile.

With respect to Finke '090 in view of Pickering et al., Pickering et al. refer to works suggesting that active components against certain E. coli strains include oligosaccharides (Table 1, page 335). Pickering et al. do not indicate the activity of all oligosaccharides but do indicate an active fraction of glycans. However, a large glycan group does not provide a useful teaching of active substances. The data also does not indicate the useful combinations of structurally defined oligosaccharides against diarrhea-causing E. coli as defined in the present specification.

In summary, one of ordinary skill in the art would not find the structurally defined oligosaccharide compositions of the present invention to be obvious in view of Finke '090. Zopf and Pickering et al. do not overcome this deficiency since these compositions are not defined in either Zopf or Pickering et al. Rather, Zopf discloses that only certain oligosaccharide species are active against specific pathogens, and Pickering et al. disclose that oligosaccharides are included among components effective against certain E. coli strains. However, neither Zopf nor Pickering et al. disclose the activities of the oligosaccharides defined in the present invention.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Finke '090 in view of Zopf or Pickering et al. fail to disclose all of the claim limitations of independent claim 92, and those claims dependent thereon. Accordingly, the combinations of references do not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

Conclusion

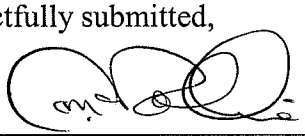
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Registration No. 58,258, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: December 18, 2009

Respectfully submitted,

By 

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